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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,638	12/09/2003	Carl D. Wahlstrand	1023-342US01	5013

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EXAMINER

GREENE, DANA D

ART UNIT PAPER NUMBER

3762

DATE MAILED: 07/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/731,638

Applicant(s)

WAHLSTRAND ET AL. C

Examiner

Dana D. Greene

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>10-28-04 &amp; 6-20-05</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

The information disclosure statement filed 10-28-04 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the date is not supplied. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16 stands rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In this application, the recitation of the limitation "the flexible tether member" in claim 16 is considered indefinite because the claim lacks antecedent basis.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 3762

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5-10, 17, 18 stand rejected under 35 U.S.C. §102(b) as being anticipated by Meltzer (US 5,645,586, hereinafter "Meltzer"). Meltzer is considered to disclose:

a first module including a first housing and first operative component within the first housing (see col. 3, ln. 20-35, fig. 2, Meltzer). The disclosed segment 23 is considered to anticipate the claimed first module because both configurations are adapted to conform to the implant site within the patient and to receive components of the IMD capable of delivering stimulus or therapy to the patient. In this connection, Meltzer teaches an electronic assembly contained within the first housing;

a second module including a second operative component (see col. 3, ln. 20-35, fig. 2, Meltzer). The disclosed segment 24 is considered to anticipate the claimed second module because both devices are flexible interconnected structures and include electronics that control the monitoring and/or therapy delivery functions of the implantable medical device;

a flexible overmold that covers the second module and partially covers the first module wherein the first housing extends out of the overmold for receipt in a first recess in a cranium of a patient (see abstract, col. 4, ln. 44-49, Meltzer). The disclosed biocompatible polymer coating is considered to anticipate the claimed overmold because both materials are flexible enough to allow for easy manipulation during

Art Unit: 3762

implantation such that they allow the implantable device to conform to the cranium or other body part.

With reference to claims 2 and 7, Meltzer is considered to disclose:

the implantable medical, wherein the first housing is substantially cylindrical (see col. 4, ln. 1-9, fig. 2, Meltzer). The disclosed housing segment is considered to anticipate the claimed first housing because both configurations have a cylinder shape which allow easier receipt into a cylindrical recess in the cranium or easier implantation within the periphery of a patient.

Referring to claims 5-6, Meltzer is considered to disclose a third module that includes a third operative component and wherein the third module includes a third housing, and wherein the flexible overmold partially covers the third module wherein the third housing extends out of the overmold for receipt in a second recess in a cranium of a patient (see col. 4, ln. 44-56, Meltzer). The disclosed housing segment is considered to anticipate the claimed third module because all modules are at least partially encapsulated and are integrated into a desired form factor and at flexible points have relative inter-module motion.

With reference to claim 8, Meltzer is considered to disclose an overmold covering the third module (see col. 4, ln. 44-48, Meltzer). The disclosed biocompatible polymer is considered to anticipate the claimed overmold because both coat the entire module with a flexible material that can be shaped to contour to the cranium.

Referring to claim 9, Meltzer is considered to teach an implantable medical device, wherein the first operative component comprises control electronics and a

Art Unit: 3762

therapy delivery circuit within the first housing (see col. 1, ln. 10-20, col. 3, ln. 30-35, and col. 4, ln. 49-63, Meltzer). The disclosed component is considered to anticipate the claimed operative component because both are capable of administering therapy to a patient. Meltzer and the claimed invention teach the delivery and generation of electrical stimulation. In this connection, Meltzer teaches therapy delivery circuitry comprised of circuits for the generation of electrical stimulation in the form of pulses, such as capacitors.

With regards to claim 10, Meltzer is considered to disclose:

the implantable medical device, wherein the therapy delivery circuit comprises a pulse generator (see col. 1, ln. 10-20, Meltzer). The disclosed pulse generator is considered to anticipate the claimed pulse generator because both are implanted within a patient's body to monitor conditions and/or deliver some type of therapy.

Referring to claim 17, Meltzer is considered to disclose:

the implantable medical device, wherein the flexible overmold comprises silicone (see col. 2, ln. 18-25, Meltzer). The disclosed biocompatible material (silicone) is considered to anticipate the claimed silicone overmold because both materials are flexible enough to integrate modules into a desired form factor.

With reference to claims 18- 21, Meltzer is considered to disclose:

the flexible overmold comprised of at least two materials (see col. 2, ln. 18-25, Meltzer). The disclosed group of biocompatible material is considered to anticipate the claimed group of two materials because both yield elastically and comply with the contour of a device implantation site and couple the first and second modules.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 4, and 11-14 are rejected under 35 U.S.C. §103(a) as being unpatentable over Meltzer in view of Reischl et al. (US 6,176,879 B1, hereinafter "Reischl"). Referring to claims 3, 4, 13, and 14, Meltzer is considered to disclose the claimed invention as discussed above except for the claimed recharge coil. It would have been obvious to one of ordinary skill in the art to combine the teachings of Meltzer with the receiving coil of Reischl for the purpose of inductively receiving energy from an external recharging unit through the skin of the patient to recharge the power source.

With reference to claims 11-12, Meltzer is considered to disclose the claimed invention as discussed above except for the claimed rechargeable power source. However, Reischl is considered to disclose the claimed rechargeable power source (see col. 2, ln. 40-48, Reischl). It would have been obvious to one of ordinary skill in the art to combine the teachings of Meltzer with the rechargeable power supply unit of Reischl for the purpose of providing power to the individual components to ultimately deliver therapeutic agents to the patient and sensing physiological parameters.

Claims 15 and 16 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Meltzer in view of Reischl et al. (US 6,176,879, hereinafter "Reischl"). Meltzer is considered to disclose the claimed invention as discussed above, under the anticipatory

Art Unit: 3762

rejection, except for the claimed flexible tether member. However, Reischl teaches a tether member that connects the third module to the overmold (see col. 1, ln. 35-55, Reischl). It would have been obvious to one of ordinary skill in the art to combine the teachings of Meltzer with the flexible silastic flap of Reischl for the purpose of allowing substantial movement of the modules relative to other modules or housings.

With reference to claims 22-23, Meltzer discloses the claimed invention except for the heights of the individual housing. It would have been an obvious matter of design choice to change the housing heights or keep them equal, since applicant has not disclosed that height differences solve any stated problem or is for any particular purpose and it appears that the invention would perform equally well with equal heights.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana D. Greene whose telephone number is (571) 272-7138. The examiner can normally be reached on M-F 9-6.

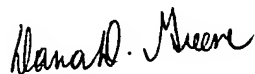
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-7138. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-0276.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

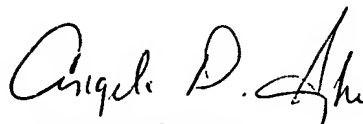


Art Unit: 3762

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Dana D. Greene



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